

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF TEXAS  
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA  
*ex rel.* PETER HUESEMAN,

Plaintiff,

v.

No. SA-14-CA-00212-XR

PROFESSIONAL COMPOUNDING  
CENTERS OF AMERICA, INC.,

Defendant.

**STIPULATED PROTECTIVE ORDER**

To expedite the flow of discovery material between the parties, facilitate the prompt resolution of disputes over confidentiality, adequately protect individually identifiable health information, proprietary information, and other confidential information, and ensure that protection is afforded only to materials so entitled, it is, pursuant to the Court's authority under Federal Rule of Civil Procedure 26(c), and with the consent of the Parties, ORDERED as follows:

1. As used herein, "Protected Material" means documents, electronically stored information, or other tangible things that contain "Protected Health Information" or "Confidential Information," as defined in Paragraphs 3 and 4 below.

2. "Document" shall mean all items listed in Federal Rule of Civil Procedure 34(a)(1)(A) & (B).

3. "Protected Health Information" or "PHI" includes certain individually identifiable health information (defined as health information that is connected to a patient's name, address, Social Security number or other identifying number, including HIC number) that may be subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, the provisions of 45 C.F.R. §§ 164.102-164.534,

the provisions of 42 U.S.C. § 1306, or for which there may be no waiver by the patient to produce the records to an entity outside one of the Parties.

a) The Court finds that this Order is a “qualified protective order” within the meaning of 45 C.F.R. § 164.512(e)(1)(v).

b) The parties may produce PHI in accordance with this Protective Order pursuant to their obligations to make disclosures under Federal Rule of Civil Procedure 26(a) and in response to discovery requests in this litigation. All patient identifiable information shall be designated “confidential” and may be used and/or disclosed in accordance with the terms of this Protective Order and 45 C.F.R. § 164.512(e)(1)(v).

4. “Confidential Information” shall mean information not already publicly available that constitutes: (i) any information subject to protection under the Privacy Act, 5 U.S.C. § 552a; (ii) personal or financial information that would properly be redacted from any public court filing pursuant to Federal Rule of Civil Procedure 5.2, or (iii) trade secrets, confidential or proprietary financial information, research and development information that has not been disclosed to third parties and the disclosure of which would lead to competitive or financial injury or potential legal liability to third parties, operational data, business plans, and competitive analyses, personnel files, personal information that is protected by law, and other sensitive information that, if not restricted as set forth in this order, may subject the producing or disclosing person to competitive or financial injury or potential legal liability to third parties.

5. “Litigation” is understood to include all appellate proceedings or the expiration of time to commence such appellate proceedings related to this action.

**Designation of Protected Material**

6. **Documents.** Documents produced during discovery by either party shall be subject to the following procedure: The parties shall not redact PHI or Confidential Information contained in documents and shall produce unredacted documents to all other parties to this litigation by designating the documents as “confidential” in the following manner:

- a) For documents produced in paper or an electronic form that allows endorsements or similar designation on the image, the parties shall mark each page of the document asserted to contain Protected Material. The parties shall use “CONFIDENTIAL – PHI” for documents that contain Protected Health Information and “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” for documents containing Confidential Information.
- b) For electronic information that is provided in native form or a format that is not amenable to visible endorsement on the image, the designation of Protected Material shall be made by branding the slip-sheet for the document, in the lower-right corner, with either “CONFIDENTIAL – PHI” or “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER,” as appropriate. The media on which the Protected Material is provided (e.g., CD, DVD, external hard drive) also must be and remain plainly labeled with “CONFIDENTIAL – PHI” or “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” unless and until the protection of the data within the media is removed. Any copying or transferring of electronic files that are designated as Protected Material must be done in a manner that maintains the protection for all copies, including, but not limited to, in the filename(s) and the location where the copies are stored and where users access the material.

7. **Interrogatory Answers and Responses to Requests for Admission.** The parties shall designate Protected Material contained in interrogatory answers or responses to requests for admissions by placing within the answer or response: The following response is “CONFIDENTIAL – PHI” or “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER.”

8. **Protected Material in Depositions.** Subject to the requirements of Paragraph 18 below, during a deposition the parties may show deponents documents or other discovery material that has been designated as Protected Material. Information disclosed at a deposition may be designated by any party as Protected Material by indicating on the record at the deposition that the testimony is confidential and subject to the provisions of this Protective Order and the reasons for the assertion. Additionally, and alternatively, any party may also designate information disclosed at a deposition as Protected Material by notifying all counsel in writing within thirty (30) days of receipt of the official deposition transcript or copy thereof (or written notification that the transcript is available), listing the specific pages and lines of the transcript and/or any exhibits that should be treated as Protected Material. The entire deposition transcript (including any exhibits not previously produced in discovery in the litigation) shall be treated as Protected Material under this Protective Order until the expiration of the above-referenced 30-day period for designation, except that the deponent (and his or her counsel, if any) may review the transcript of his or her own deposition during the 30-day period subject to this Protective Order upon executing the required Acknowledgement attached to this Order. After a party designates portions of a deposition transcript as Protected Material, the front of the original and each copy of the deposition transcript shall be marked “This deposition transcript includes CONFIDENTIAL INFORMATION [OR CONFIDENTIAL PHI] SUBJECT TO PROTECTIVE ORDER.” If the deposition was filmed, both the recording storage medium (i.e., CD or DVD) and its container shall also be labeled: “This

deposition transcript includes CONFIDENTIAL INFORMATION OR PHI SUBJECT TO PROTECTIVE ORDER.” Only those portions of the deposition transcript that are designated as containing Protected Material shall be governed by this Order. Nothing in this Order restricts the use of any portion of a deposition transcript that has not been designated as Protected Material.

9. **Documents or Information Obtained from Third Parties.** Documents or information produced by a non-party may be designated as Protected Material by the non-party. Further, the documents or information produced by a non-party shall be treated as Protected Material, whether or not they are designated as such, for sixty (60) days after receipt of the documents or information to allow a party to review the material for PHI or Confidential Information. In the event a party believes that documents or information produced by a non-party contain Protected Material, the party may designate the documents or information as Protected Material in accordance with the provisions of this Protective Order within sixty (60) days after receipt of the documents or information. The party making such designations shall request that the third party produce overlays of the designated documents containing the markings described in Paragraph 6 above. If no party timely designates Protected Material within a non-party production, none of the documents or information will be treated as Protected Material, unless designated as Protected Material by the non-party or unless later designated as Protected Material in accordance with Paragraph 13 (“No Waiver”).

10. **Documents Produced During the Government’s Investigation Prior to Intervention (“Pre-Suit Materials”).** The Court acknowledges the parties’ disagreement over PCCA’s designation of “Confidentiality” of all Pre-Suit Materials and whether PCCA is required to review specific portions of its Pre-Suit Materials that PCCA designates as responsive to any discovery request. Except as otherwise provided, the parties agree to treat all Pre-Suit Materials as “Protected

Materials” for purposes of this Protective Order, reserving all rights to challenge any Confidentiality designation in the Pre-Suit Materials pursuant to the procedures set forth in this Protective Order.

**11. Civil Investigative Demand (CID) Examinations Taken During the Government’s Investigation Prior to Intervention.** The transcripts of CID Examinations taken pursuant to 31 U.S.C. § 3733 during the Government’s pre-suit investigation (“Pre-Suit CID Examination”) are deemed Protected Materials. Accordingly, no party is required to designate portions of such Pre-Suit CID Examinations pursuant to Paragraph 8 of this Order. Notwithstanding the foregoing, the exhibits attached to any Pre-Suit CID Examination shall not be deemed Protected Materials unless the party or entity that produced the document reviews the document for Confidentiality Designations as specified under this Order and determines in good faith that the document is subject to the Confidentiality Designation in accordance with this Order.

**12. Good Faith Basis for Designation.** A party designating documents or information as Protected Material (“designating party”) shall do so based upon a good faith belief that the document or information is subject to protection under this Protective Order.

**13. No Waiver.** The failure to designate any documents or other discovery material as Protected Material in accordance with the terms of this Order shall not constitute a waiver of a party’s assertion that the materials are Protected Materials. In the event that discovery material is or has been produced without having been previously marked “CONFIDENTIAL – PHI” or “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER,” the producing party may notify the receiving party of the appropriate confidentiality designation and produce new hard copy, images, or slip-sheets as applicable (see Paragraph 6 above) reflecting the appropriate confidentiality

designation. Upon receipt of any such discovery material, the receiving party shall thereafter preserve such discovery material in accordance with this Protective Order.

**Challenges to Designations Under This Protective Order**

14. A party shall not be obligated to challenge the propriety of a designation of a document or other discovery material as Protected Material at the time such designation is made, and a failure to do so shall not preclude a subsequent challenge to the designation.<sup>1</sup> In the event that any party to this litigation disagrees in good faith at any stage of these proceedings with the designation of any information as Protected Material, the parties shall first try to resolve the dispute in good faith on an informal basis, such as by production of redacted copies. If the dispute cannot be resolved, the objecting party may invoke this Protective Order by objecting in writing to the party who designated the document or information as Protected Material. The designating party shall then have 14 days to move the Court for an order preserving the designated status of the disputed information. The disputed information shall remain Protected Material unless the Court orders otherwise. Failure to move for an order shall constitute a termination of the status of such item as Protected Material.

15. If the Court rules that the document or other discovery material should no longer be designated as Protected Material or if the designating party at any time withdraws the designation, the designating party shall promptly provide all other parties in the litigation with replacement documents, files, or information free from any markings or designations as Protected Material. The replacement versions shall be provided in the same format as the information that is to be replaced, unless otherwise agreed to by the parties. The presumptive time for providing the

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<sup>1</sup> The parties reserve the right to make any arguments, or seek any other appropriate relief, available to them under the law.

replacement information shall be ten (10) calendar days, but the designating party must in good faith provide the information in a reasonable time, considering any agreements of the parties, the volume of information to be re-produced, and the nature or format of the information.

**Disclosure, Use, and Handling of Protected Material**

16. All Protected Material provided by any party or nonparty in the course of this litigation shall be used solely for the purpose of preparation, trial, and appeal of this litigation and for no other purpose and shall not be disclosed except in accordance with the terms of this Order.

17. The parties and their counsel are responsible for employing reasonable measures, consistent with this Protective Order, to control access to and secure distribution of Protected Material.

18. **Disclosure of Protected Material.** Except as otherwise provided in this Protective Order, documents and other discovery materials designated as Protected Material shall only be disclosed to the following persons:

a) Counsel of record for the parties in this litigation and associated personnel necessary to assist counsel in this action, such as paralegals, litigation support, information technology, information or records management, investigative, secretarial, or clerical personnel, provided that each is first advised of the terms of this Protective Order;

b) The parties and their officers or employees, including in-house counsel, whose assistance is reasonably necessary to assist counsel in this action, provided that each is first advised of the terms of this Protective Order;

c) Actual or potential experts or consultants (and their administrative or clerical staff) retained in good faith for the purposes of this litigation, including both consulting and testifying experts, who have first signed the “Acknowledgement and Agreement to Comply with Protective



Order” in the form attached hereto as Exhibit A;

d) Jury and trial consultants and their staff and mock jurors who have first signed the “Acknowledgement and Agreement to Comply with Protective Order” in the form attached hereto as Exhibit A;

e) The Court and court personnel;

f) Court reporters, videographer services, translation service, photocopy service, document management service, records management service, graphics service or such other litigation assistance service designated by a party or party’s legal counsel in this litigation who have first signed the attached “Acknowledgement and Agreement to Comply with Protective Order”;

g) Any private mediators used in this Action and their employees who have first signed the attached “Acknowledgement and Agreement to Comply with Protective Order”;

h) Any witness who is called to testify at a deposition or hearing in this litigation concerning documents or information designated as subject to this Protective Order or who otherwise will be shown or given access to documents or information designated as subject to the Protective Order during the deposition or hearing, provided that any such person or entity is advised of the terms of this Protective Order and has first signed the attached “Acknowledgement and Agreement to Comply with Protective Order,” or provided that the Court, upon the request of any party, otherwise permits the disclosure of Protected Material to the individual; and

i) Any individuals interviewed in good faith by any of the parties for the purposes of this litigation who have first signed the “Acknowledgement and Agreement to Comply with Protective Order,” provided that the parties take reasonable steps to prevent the individuals being interviewed from making or retaining any copies of any Protected Material.

j) Any person who was an author, addressee, or intended or authorized recipient of the Protected Material and who agrees to keep the information confidential, provided that the parties take reasonable steps to prevent the individuals from making or retaining any copies of any Protected Material.

19. Counsel for the parties shall maintain, in their respective offices or storage facilities, all copies of the executed “Acknowledgement and Agreement to Comply with Protective Order” forms, as well as a list of all individuals who have signed the forms.

20. Persons receiving Protected Material pursuant to the terms of this Protective Order are prohibited from disclosing it to any person except in conformance with this Protective Order.

21. **Protected Material in Open Court.** The procedures for use of Protected Material during any hearing or the trial of this matter shall be determined by the parties and the Court in advance of the hearing or trial. This Protective Order does not apply to trial proceedings.

22. **Protected Material in Court Filings.** All Protected Material and all Pre-Suit Materials bearing the “CONFIDENTIAL” marking (“Designated Pre-Suit Materials”) shall be subject to the following procedure:

- a) All Protected Material and Designated Pre-Suit Materials attached as an exhibit to any filing shall be filed with an accompanying motion to temporarily seal such exhibit(s) for a period of thirty (30) days.
- b) If the party that produced the Protected Material and/or Designated Pre-Suit Materials seeks to extend the temporary seal, the producing party shall, within thirty (30) days of the filing of the motion to temporarily seal pursuant to Paragraph 22(a), file a motion to seal in accordance with the requirements of Local Rule CV-5.2, justifying the need for a sealing order in accordance with prevailing law.

- c) If no motion to seal the previously filed exhibits is filed within the thirty (30) day period set forth in Paragraph 22(b), the temporary seal will expire and the exhibits shall be unsealed, in which case they shall no longer be treated as Protected Material for purposes of this Protective Order.

**23. Subpoenaed or Other Compulsory Production of Protected Material.** If any party or person who has received Protected Material is asked to produce such information by a subpoena or other compulsory process for purposes of use in a separate legal action, the party or person receiving such a request shall promptly inform the designating party that such request has been made and shall allow the designating party ten (10) days to seek appropriate relief or protection from the proper court to prevent the production. The designating party shall bear the burden and expense of seeking protection of its designated Protected Material. Nothing in this Protective Order should be construed as authorizing or encouraging a subpoenaed person to disobey a lawful directive from this or another court.

**24. Disclosure to Agencies or Departments of the United States.** Nothing in this Protective Order shall prevent or in any way limit or impair the right of the United States to disclose to any of its agencies or departments, or any division or office of any such agency or department, information or materials provided in this action, including those designated as Protected Material under this Order, that relate to a potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order prevent or in any way limit or impair the use of any information provided in this action, including Protected Material, by an agency in any proceeding relating to a potential violation of law or regulation, or relating to any matter within that agency's jurisdiction; provided, however, that the agency shall be advised of the

terms of this Protective Order and maintain the confidentiality of the Protected Material in a manner consistent with the terms of this Order unless otherwise authorized by law.

25. **Disclosure to Congress.** Nothing contained in this Protective Order shall prevent or in any way limit or impair the right of the United States to provide designated Protected Material to a Congressional entity; provided, however, that the United States shall notify the Congressional entity requesting the documents that the Protected Material has been produced pursuant to this Protective Order and shall, if there are no objections interposed by the Congressional entity requesting the documents, use reasonable efforts to notify the designating party or non-party of the Congressional entity's request and the United States' response thereto.

26. **Use of Party's Own Confidential Information.** Nothing in this Protective Order shall restrict the right of any party to use its own Confidential Information for any purpose whatsoever, but if any such use results in a disclosure that causes the Confidential Information to lose its designation as Protected Material, then it shall no longer be subject to any protection under this Protective Order.

27. **Inadvertent Disclosure of Protected Material.** If a party in receipt of Protected Material ("receiving party") discovers that it, or a person to whom it has disclosed Protected Material in accordance with this Protective Order, has inadvertently disclosed Protected Material subject to this Protective Order to any person not authorized under this Protective Order, the receiving party must: (a) notify in writing the designating party of the inadvertent disclosure, providing with such notice the identity of the person to whom the Protected Material was disclosed and, upon request of the designating party, details concerning the circumstances of the disclosure, (b) use its best efforts to retrieve all copies of any Protected Material, (c) inform the person to whom the inadvertent disclosure was made that the documents or information are Protected

Material subject to this Protective Order and request that the person who received the inadvertent disclosure agree to be bound by the terms of this Protective Order by executing the attached “Acknowledgement and Agreement to Comply with Protective Order.”

**Disposition of Protected Material at the Conclusion of this Litigation**

28. Except as provided in this Protective Order, within 90 days of the conclusion of this litigation, including appeals, the parties shall (a) destroy or delete all items designated as Protected Material and certify in writing that the items have been destroyed or deleted, or (b) return them to the designating party, depending upon the designating party’s stated reasonable preference, except materials that exist on back-up tapes or similar systems. Materials that exist on back-up tapes, systems, or similar storage need not be immediately deleted or destroyed, and, instead, such materials should be overwritten and destroyed in the normal course of business. Until they are overwritten in the normal course of business, the receiving party will take reasonable steps to limit access, if any, to the persons necessary to conduct routine IT and cybersecurity functions. In the course of disposing of information in its possession under this paragraph, the receiving party also will take reasonable steps to notify persons to whom it distributed Protected Material pursuant to this Order that such information should be returned to the receiving party or destroyed by the person possessing the information with written confirmation to receiving party.

29. Notwithstanding the above provision, counsel for the parties are entitled to retain an archival copy of all pleadings, affidavits, motion papers, deposition and trial transcripts, legal memoranda, correspondence, deposition and trial exhibits, expert reports, briefs, other papers filed with the Court, and any other parts of the trial record, as well as notes and other documents constituting the work product of litigation counsel, even if these items contain or reflect Protected Material, so long as the these items remain clearly marked to reflect that the information contained

therein is Protected Material subject to this Protective Order. In particular, attorneys for the United States may maintain copies of any Protected Material in their case file, as well as copies of any notes or summaries containing such Protected Material subject to the Federal Records Act, 44 U.S.C. § 3101, *et seq.*

**General Provisions**

30. All documents containing Protected Health Information that the parties previously produced to one another prior to the entry of this Protective Order shall be deemed Protected Material subject to this Order.

31. This Protective Order does not constitute a ruling on the question of whether any particular document or information is properly discoverable or admissible and does not constitute any ruling on any potential objection to the discoverability of any document or information.

32. For good cause shown, any party may seek to modify or supplement the terms of this Protective Order by first attempting to obtain the consent of the other parties. The parties shall attempt to resolve the issue of any such modification or supplementation among themselves through good faith efforts before seeking judicial intervention. If the parties are not able to reach an agreement, the party seeking the modification or supplementation may file an appropriate motion with the Court upon notice to the other parties.


33. Notwithstanding the previous paragraph, the parties may stipulate to extend the time periods that do not directly impact filing deadlines—*i.e.*, the deadlines set forth in paragraphs 8, 9 (meet and confer deadlines only), 14, 22, and 28.

34. Upon final termination of this litigation, whether by settlement, dismissal, or other disposition, the provisions of this Protective Order shall continue to be binding upon all persons or entities who are subject to the terms hereof (including former employees of any party who

received Protected Material). The Court shall retain continuing jurisdiction to enforce the terms of this Order.

**IT IS SO ORDERED.**

DATED: November 28, 2022

A handwritten signature in blue ink, consisting of a large, stylized loop followed by a horizontal line extending to the right.

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XAVIER RODRIGUEZ  
UNITED STATES DISTRICT JUDGE